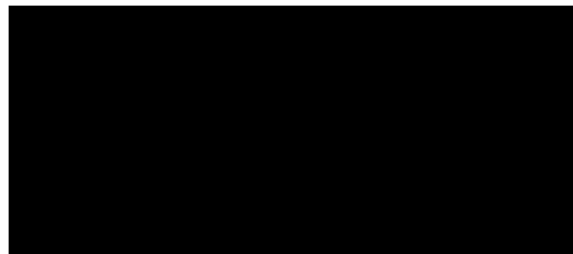




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

Xiao Huang
International Flavors and Fragrances Inc.
800 Rose Lane
Union Beach, NJ 07735



Re: PMN.P-16-0510

Dear Ms. Huang,

This letter provides you notice of the United States Environmental Protection Agency's (EPA's) intent to issue a direct final significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2604(a)(2), for the chemical substance described in the premanufacture notice (PMN) referenced above (Jeffamine Diacrylamide).

EPA's initial review indicates that the chemical substance is not likely to present an unreasonable risk of injury to health or the environment under the conditions of use described in the PMN (including any amendments). However, EPA has preliminarily determined that reasonably foreseen changes from the conditions of use described in the PMN could result in increased exposures to the chemical substances and changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substances.

In reviewing this PMN, EPA identified human health concerns from exposure to the chemical substance via inhalation and dermal routes which would be present if the chemical substance were used in a manner other than as identified in the PMN. The concern is based on test data and/or ecological structure-activity relationship (ECOSAR) analysis of test data for the chemical or equivalent information on an analog.

If the SNUR becomes effective, EPA expects to determine, pursuant to TSCA section 5(a)(3)(C), 15 U.S.C. § 2604(a)(3)(C), that the PMN substance is not likely to present an unreasonable risk of injury to health or the environment, based on the data before the Agency and the risk assessment conducted for the conditions of use identified in the PMN, and because any reasonably foreseen activities involving the chemical substance would require further notification and evaluation by EPA under section 5(a) of TSCA.

The SNUR would establish the following as significant new uses in 40 C.F.R. 721 Subpart E for the new chemical substance:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f). It is a significant new use to use the PMN substance at a concentration greater than 2% by weight in the final end product.

The SNUR would require submission of a significant new use notice (SNUN) to EPA at least 90 days before:

- i. any domestic manufacture of the PMN substance;
- ii. any use of the PMN substance above a maximum concentration of 2% by weight in the formulation of the final product.

The recordkeeping requirements described at 40 C.F.R. § 721.125(a), (b), (c), and (i) would also be applicable to the chemical substance. The SNUR would apply to all persons, including to your company, your customers for the chemical substance, and any other manufacturer or processor of the chemical substance.

Section 5(a)(1)(B) of TSCA, 15 U.S.C. § 2604(a)(1)(B), provides that no person (including you, the PMN submitter) may manufacture (including import) or process a chemical substance for a use designated by EPA as a "significant new use" unless that person submits a SNUN to EPA, and EPA reviews that notice and makes a determination pursuant to section 5(a)(3) of TSCA, 15 U.S.C. § 2605(a)(3). This review requires EPA to assess potential risk under the conditions of use and impose any appropriate regulatory control actions.

For many SNURs, the preamble in the Federal Register notice for the SNUR suggests testing that would be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who submit SNUNs are encouraged, but not required, to conduct the suggested testing on the substance. Any testing identified by EPA for your chemical substance that would be useful will be specified in the preamble.

If you choose not to suspend the review period, EPA would not be able to use the SNUR as part of the basis for its section 5(a)(3) determination, and the Agency might be required to issue an order under section 5(e) or section 5(f) of TSCA. In order for there to be sufficient time to promulgate the SNUR, and for the SNUR to go into effect before the end of the review period, the Agency requests that you suspend the PMN review period until after the effective date of the SNUR. If EPA receives comments on the SNUR, those comments may cause EPA to reassess its current expectation as to the appropriate determination for the chemical under TSCA section 5(a)(3).

If you have any questions or comments, please contact [REDACTED]
[REDACTED]

Sincerely,



Greg Schweer, Chief
New Chemicals Management Branch
Chemical Control Division (7405 M)